In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-38V

UNPUBLISHED

KRISTIE RINIER, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: May 15, 2024 Special Processing Unit (SPU); Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA); Six Month Severity Requirement

Emily Beth Ashe, Anapol Weiss, Philadelphia, PA, for Petitioner.

Mitchell Jones, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On January 4, 2021, Kristie Rinier filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered on October 29, 2019. Petition at 1.

For the reasons discussed below, I find Petitioner has established that she suffered the residual effects of her injury for more than six months, and is otherwise entitled to compensation.

[1] In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

Petitioner filed this matter on January 4, 2021. Respondent filed a Rule 4(c) Report opposing compensation on October 26, 2022. Respondent's Rule 4(c) Report ("Report"), ECF No. 31. Respondent argues that Petitioner cannot meet the Vaccine Act's "severity" requirement, and also cannot meet the Table requirements because her pain did not occur within 48 hours of vaccination and another condition would explain her symptoms. Report at 6-7. On February 6, 2023, Petitioner filed a motion for a ruling on the record in favor of the claim. Petitioner's Motion for a Ruling on the Record ("Mot."), ECF No. 36. Respondent did not file a response. The matter is ripe for resolution.

II. Factual Background

The medical records reveal that Petitioner was a registered nurse who previously suffered from some other conditions, including a cervical radiculopathy that resulted in an image-guided cervical spine injection in 2008. Ex. 3 at 1.

Petitioner received a flu vaccine in her left shoulder on October 29, 2019. Ex. 1 at 1. On November 29, 2019, she reported shoulder pain (beginning "immediately after the [flu] shot") to her primary care provider, Dr. Shirlene Moten. Ex. 2 at 1. Dr. Moten noted that the onset of Petitioner's pain was sudden. *Id.* Petitioner was diagnosed with subacromial bursitis, prescribed prednisone and Flexeril, and x-rays were ordered. *Id.*

Petitioner presented to her primary care provider on December 23, 2019, with complaints including ongoing left arm pain. Ex. 7 at 9. She was referred to physical therapy. *Id.* at 12-13.

On January 10, 2020, Petitioner had an initial evaluation for physical therapy. Ex. 3 at 10. She reported that her left shoulder pain and range of motion issues started immediately after her October 29, 2019 flu vaccine. *Id.* She also complained of hand numbness and pain between her third and fourth fingers of her left hand. *Id.* An examination showed reduced range of motion. *Id.* at 8.

Petitioner attended eight physical therapy sessions between January 10 and February 4, 2020. Ex. 3 at 5-26. Additionally, on February 4, 2020, Petitioner stated that "her elbow has been bothering her a lot for a while now," and that she "has been playing phone tag with her neurologist" to make an appointment. *Id.* at 26.

Petitioner complained of pain, numbness, and paresthesias in her left upper arm to neurologist Dr. Maureen Gottfried on February 19, 2020. Ex. 6 at 2. Dr. Gottfried noted

that Petitioner's arm pain "started after she was given the Flu shot", that onset was sudden, and that it had been occurring for three and a half months. *Id.* An examination showed Petitioner exhibited a decrease range of motion and tenderness to palpitation. *Id.* at 3. A Medrol Dosepak and MRI were ordered. *Id.* at 4. The MRI was performed on February 28, 2020, and it showed interstitial splits and tendinosis, but no other significant pathology. Ex. 4 at 1-2.

Petitioner presented to Dr. Kevin McHale, an orthopedist, on March 11, 2020, for left shoulder pain that had been ongoing since her October 19, 2019 flu vaccine. Ex. 3 at 1. She also stated that she had neck pain, numbness, and paresthesia extending to her long and ring finger of her left hand. *Id.* An examination showed limited range of motion with pain, positive impingement signs, but normal strength. *Id.* at 3. Petitioner was diagnosed with left rotator cuff tendinitis and cervical radiculopathy, and Dr. McHale noted that "[d]ue to persistent pain…in fingers… [p]atient has been followed by a neurologist for cerfical radiculopathy…." *Id.* A subacromial steroid injection was administered and she was directed to follow-up with a neurologist to address her radiculopathy.

Petitioner presented to D.O. Tara Vogdes on August 12, 2020, for complaints of calf pain for two months. Ex. 7 at 5. The record also stated that Petitioner's "[l]eft shoulder pain occurred immediately after shot. Some limitations of [range of motion] ever since." *Id.* Referred to vascular surgeon. No mention of arm pain.

Petitioner has submitted two affidavits in support of her petition. In the first, she explained that she continued to experience pain and tenderness at least until February 8, 2021. Ex. 5. In the second, she detailed her course of treatment and stated that she received a vaccination at the start of an overnight shift on October 29, 2019, and that she had pain and stiffness "by the time my manager arrived the next morning…" Ex. 8 at 1. Additionally, Petitioner stated that she did no seek medical treatment until November 29, 2019 because she "anticipated and hoped that the pain and stiffness …would subside." *Id.* at 2. Further, she was self-treating her pain with an at-home exercise program and medications. *Id.* Petitioner also explained that she was in a car accident in 2008 and developed syringomyelia "around C5-C6", but that she has no recollection of being diagnosed with cervical radiculopathy. *Id.* at 3.

Joseph Ignatovig, Petitioner's cohabiting partner, also submitted an affidavit in support of her claim. Ex. 9. He states that he recalls Petitioner returning from work on October 30, 2019, and complaining of severe pain since the flu shot hours earlier. *Id.* at 1. Further, he states that Petitioner continues to experience pain, soreness, weakness, and limited range of motion in that arm. *Id.* at 2.

Teresa Eames, Petitioner's coworker, submitted an affidavit as well. Ex. 10. She also recalled Petitioner reporting shoulder pain immediately following her vaccination. *Id.* at 1.

III. Legal Standard

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

In particular, a petitioner must establish that she suffered an injury meeting the Table criteria (*i.e.* a Table injury), in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. If a petitioner establishes a Table injury the burden shifts to respondent to establish a more likely alternative cause. Section 13(a)(1)(A), 11(c)(1)(C)(i), 14(a). If a petitioner cannot establish a Table injury, or she may pursue causation-in-fact under the legal standard set forth in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

> (iv) No other condition or abnormality is present that would explain the patient's symptoms (*e.g.* NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

In addition to causation, a petitioner must also meet the requirements establishing that the vaccine received is "covered" by the Program, the duration and severity of petitioner's injury, and the lack of other award or settlement.[3] With regard to severity, a petitioner must show that she suffered the residual effects or complications of her injury or condition for more than six months after the administration of the vaccine. § 11(c)(1)(D)(i); *see Song v. Sec'y of Health & Hum. Servs.,* 31 Fed. Cl. 61, 65-66 (1994), aff'd, 41 F.3d 1520 (Fed. Cir. 2014) (noting that a petitioner must demonstrate the six-month severity requirement by a preponderance of the evidence). Finding that petitioner has met the severity requirement cannot be based on petitioner's word alone, though a special master need not base their finding solely on medical records. Section 13(a)(1); *see Colon v. Sec'y of Health & Hum. Servs.*, 156 Fed. Cl. 534, 541 (2021). Severity must be established regardless of whether the claim arises under the Table or is a causation-in-fact claim.

A. Severity Requirement

The first issue to be resolved is whether Petitioner has demonstrated that she suffered "residual effects or complications of [the injury alleged] for more than six months after the administration of the vaccine," as required for eligibility under the Vaccine Program. Section 11(c)(1)(D)(i).

There is no dispute that Petitioner received the flu vaccine on October 29, 2019, and she therefore must demonstrate by preponderant evidence that her residual symptoms continued at least through April 29, 2020 (assuming onset of pain the day of vaccination). *See, e.g., Herren v. Sec'y of Health & Human Servs.*, No. 13-100V, 2014 WL 3889070, at *2 (Fed. Cl. Spec. Mstr. July 18, 2014); *see also Hinnefeld v. Sec'y of Health & Human Servs.*, No. 11-328V, 2012 WL 1608839, at *4-5 (Fed. Cl. Spec. Mstr. Mar. 30, 2012) (dismissing case where medical history revealed that petitioner's injury resolved less than two months after onset).

[3] In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* § 11(c)(1)(A)(B)(D)(E).

The record establishes that Petitioner's initial treatment occurred over approximately four and a half months, or until March 11, 2020. The records also state that she experienced range of motions issues at least until August 12, 2020. Ex. 7 at 5.

Respondent argues that Petitioner did not seek treatment for her shoulder after March 11, 2020, and that there are no additional reports of shoulder pain after that time. Report at 6-7. However, as stated above, there are references to continued sequelae of Petitioner's SIRVA at least until August 2020.Such a record is adequate evidence of severity to meet the preponderance evidentiary standard. It is likely that Petitioner's symptoms persisted into, and just beyond, the spring of 2020, despite the cessation of treatment and subsequent gap. However, the consistently light history of treatment suggests a mild injury - which will impact what damages are proper.

B. Factual Findings Regarding a Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence demonstrates that Petitioner has satisfied the QAI requirements for a Table SIRVA.

1. Petitioner Had No Prior Left Shoulder Condition or Injury that would Explain her Symptoms

The first requirement for a Table SIRVA is a lack of problems associated with the affected shoulder prior to vaccination that would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i). Respondent claims that Petitioner had a history of radiculopathy, and she cannot meet this requirement. Report at 7. Petitioner explained in her affidavit that she was diagnosed with Syringomyclia following a car accident in 2008. Further, she states that she has no recollection of being diagnosed with radiculopathy. Ex. 8 at 3. The earlier accident may explain certain symptoms, including the tingling and numbness in her fingertips, but would not completely explain the symptoms associated with Petitioner's SIRVA, including pain and reduced range of motion.

2. Onset of Petitioner's Injury Occurred within Forty-Eight Hours of her Vaccination

The medical records preponderantly establish onset of injury close-in-time to vaccination. Petitioner first reported shoulder pain on November 29, 2019, one month after her vaccination, and noted that the pain began "immediately after the [flu] shot." Ex. 2 at 1. Thereafter, Petitioner continued to link her shoulder pain temporally to the flu vaccine. *See* Ex. 3 at 10 (record from January 10, 2020, stating that Petitioner's pain and

range of motion deficits started immediately after her October 29, 2019 flu vaccine); Ex. 6 at 2 (record from February 19, 2020, stating her pain started after a flu shot).

Respondent argues that Petitioner has no contemporaneous records falling within the 48-hour post-vaccination period. Report at 7. Even so, a finding of proper onset can be made based on such a record. Program petitioners are not required to seek medical care within 48-hours of vaccination. Further, as noted above, Petitioner consistently linked her shoulder pain to the September flu vaccine.

Additionally, the relevant medical records show that Petitioner reported shoulder pain in a relatively timely manner, when measured from the date of vaccination. Further, she stated in her affidavit that her delay was because she hoped her pain and stiffness would subside. It is common for SIRVA petitioners to delay seeking treatment, thinking the injury will resolve on its own, especially since patients are often told by medical providers at the time of vaccination to expect some soreness and pain for a period of time after. Here, the added detail of onset did not "wait" for months before being provided, but began to be reported in a reasonable time post-vaccination.

Accordingly, there is preponderant evidence that establishes the onset of Petitioner's left shoulder pain more likely than not occurred within 48-hours of vaccination.

3. Petitioner's Pain was Limited to her Left Shoulder

Petitioner's pain was limited to her left shoulder. Respondent does not contest this aspect of Petitioner's claim. References to pain and numbness in Petitioner's extremities are present in the record, however they are likely do to an unrelated issue and not her SIRVA.

4. There is No Evidence of Another Condition or Abnormality

The last criteria for a Table SIRVA state that there must be no other condition or abnormality which would explain a petitioner's current symptoms. 42 C.F.R. § 100.3(c)(10)(iv). Respondent argues that Petitioner had a history of cervical radiculopathy and the symptoms are consistent with that condition. Report at 7. However, this is not accurate. As described above, Petitioner had a history of pain associated with a car accident in 2008. Further, her symptoms, including pain and reduced range of motion, are consistent with a SIRVA.

Admittedly, pain reported in Petitioner's elbow and finger at times may be unrelated to Petitioner's SIRVA – but that kind of complaint or injury can be disregarded in

calculating damages. The mere existence of such record complaints does not defeat a showing that Petitioner not only did experience shoulder-specific pain, but that most of her complaints and treatment efforts were aimed at that. Accordingly, preponderant evidence supports this Table element as well.

C. Other Requirements for Entitlement

In addition to establishing a Table injury, a petitioner must also provide preponderant evidence of the additional requirements of Section 11(c). Respondent does not dispute that Petitioner has satisfied these requirements in this case, and the overall record contains preponderant evidence to fulfill these additional requirements.

The record shows that Petitioner received a flu vaccine intramuscularly on October 29, 2019, in the United States. Ex. 1 at 1; *see* Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i)(I) (requiring administration within the United States or its territories). There is no evidence that Petitioner has collected a civil award for her injury. Ex. 5; Section 11(c)(1)(E) (lack of prior civil award).

Based upon all of the above, Petitioner has established that she suffered a Table SIRVA. Additionally, she has satisfied all other requirements for compensation. I therefore find that Petitioner is entitled to compensation in this case.

Conclusion

In view of the evidence of record, I find that there is preponderant evidence that Petitioner satisfies the QAI requirements for a Table SIRVA. Further, based on the evidence of record, I find that Petitioner is entitled to compensation.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master